DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
FAX: 404-253-1202

94693d

January 27, 2003

VIA FEDERAL EXPRESS

Dr. Volker E. Dube
CEO/Medical Director
Walter L. Shepeard Community Blood Center, Inc.
1533 Wrightsboro Road
Augusta, GA 30904

WARNING LETTER
(03-ATL-10)

Dear Dr. Dube:

During an inspection of Walter L. Shepeard Community Blood Center, Inc. located at 1533 Wrightsboro Road, Augusta, GA, on 9/16 – 10/09/02, FDA Investigators documented numerous violations of Title 21, Code of Federal Regulations (21 CFR) Parts 600 - 680 and Part 211. Most biological products are included in the definition of a drug under the Federal Food Drug and Cosmetic (FD&C) Act, Section 201(g)(1). The Current Good Manufacturing Practice (CGMP) regulations for Blood and Blood Components (21 CFR 606) assure the production of safe, pure, and effective products by all licensed and unlicensed facilities. The CGMP regulations for Finished Pharmaceuticals (21 CFR 211) are also applicable to blood and blood products intended for transfusion and for those used for further manufacture of injectable products. The violations documented in Parts 600 - 680 and Part 211 cause your product to be adulterated, as defined in Section 501(a)(2)(B) of the FD&C Act, as follows:

1. Failure to have in place written validation protocols, maintenance of complete and accurate documentation of the performance of the validation protocols, and an analysis of the results by the blood bank computer system [21 CFR 211.68(a) & (b)] in that:

   a. You have no written protocol requiring or describing the validation of the [redacted] ABO/RH machine, including accept/reject criteria, number of samples per run, stress testing, and investigations of samples classified as "Invalid" by the blood bank computer system.

   b. Record review of the initial and update validation for the [redacted] ABO/RH automated equipment disclosed that the donation dates for various donors were different from the donation dates listed in the validation data and that two of the sample numbers were "invalid" when entered into the [redacted] computer system. The firm's records must be adequate to demonstrate that the validation data from the [redacted] ABO/RH automated equipment is accurate.

   c. Parallel testing of the [redacted] analyzer was to be performed for 30 days according to the "Validation [redacted] protocol, dated 9/01, however, it was only performed for 12-15 days and did not include acceptable values for both Pre & Post Platelet Pheresis counts. In addition, that protocol, dated 9/01, did not require a sufficient degree of input/output verification, based on the complexity and reliability of the [redacted] analyzer. For

example, the protocol did not contain or even reference the validation requirements set forth in the manufacturer's instructions.

d. Some of the validation test results for the [redacted] analyzer, including some of the raw data, were missing or unavailable for review during the inspection.

2. Failure to maintain written standard operating procedures, including all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for homologous transfusion [21 CFR 606.100(b)], including, but not limited to the following:

a. Changing of reactive test results for syphilis after visual examination of the test trays from the [redacted] automated equipment.
b. Resolution of all duplicate and discrepant donor reports
c. Maintaining a Temperature Monitoring System repair log
d. Upper and lower temperature alarm limits
e. Corrective steps to be taken to resolve temperature alarms

3. Failure to follow written standard operating procedures, including all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for homologous transfusion [21 CFR 211.100(b)], including, but not limited to the following:

a. Donor [redacted] was accepted for a Plateletpheresis donation on 9/16/02. The donor had an initial platelet count of 128,000ul (acceptable range is = or > [redacted] per your firm's SOP "Plateletpheresis Donor Criteria (# H11.0S) Section 9.2, "Donor Eligibility"). A second sample was collected on 9/16/02, even though there is no written SOP that allows the collection of a second sample, and the sample was found to be 176,000ul. The donor was allowed to donate and the platelet unit was distributed. There was no documentation in the Donor Record File (DRF) to show that the initial sample had been collected and found unacceptable.

b. Donor [redacted] was accepted for a Plateletpheresis donation on 9/17/02. The donor had an initial platelet count of 146,000 ul (acceptable range is = or > [redacted] per your firm's SOP "Plateletpheresis Donor Criteria (# H11.0S) Section 9.2 "Donor Eligibility"). A second sample was collected on 9/17/02, even though there is no written SOP that allows the collection of a second sample, and the sample was found to be 159,000 ul. The donor was allowed to donate and the platelet unit was distributed.

c. Donor [redacted] was accepted for a Plateletpheresis donation on 9/17/02. Your firm's SOP "Plateletpheresis Donor Criteria" (# H11.0S) requires, under section 9.2 "Donor Eligibility," that the WBC count be < [redacted] however, on 9/17/02 the WBC count for donor [redacted] was 11,400ul. The platelet unit was distributed for transfusion.

4. Failure to maintain complete and accurate records [21 CFR 606.160 (b)(1)(ii)] in that:

   a. A computer check of five donors with a deferral of 56 days disclosed that two of the donors [redacted] were not appropriately deferred for the 56 day period. These donors were entered in the computer system with a 1-5 day deferral.

   b. The [redacted] Alarm Reports dated 8/00 through 8/6/02 did not have documentation to show that the reported [redacted] Alarm testing problems had been resolved (e.g. wrong sample numbers were pulled for retest).

5. Failure to assure that personnel have the training and experience necessary for the competent performance of their assigned function and a thorough understanding of the manufacturing operations (collection, processing, testing, storage and/or distribution) of blood and blood components [21 CFR 606.20 (b)] and [21 CFR 211.25(a)]. For example:

   a. During the start of a Plateletpheresis procedure for donor [redacted] on 9/17/02, the donor complained of extreme pain in her arm immediately after the venipuncture was performed. During this procedure a low pressure warning light came on five times. The technician restarted the procedure each time. The Director of Donor Services heard the donor complaining of the extreme pain in her arm and told the technician to remove the needle because it was in the donor's muscle, rather than the vein.

   b. On 9/17/02, donor [redacted] completed a Plateletpheresis procedure with approximately 300 ml of Whole Blood (WB) and/or Red Blood Cells (RBC) in the saline bag and tubing throughout the procedure. An entry of 0 RBC loss was documented on the donor's Plateletpheresis Procedure Record and Worksheet, dated 9/17/02, and there was no entry in the donor record file to show that the donor was deferred for 8 weeks due to the WB/RBC loss.

We acknowledge receipt of your letters, dated October 24 and November 12, 2002, submitted to this office in response to the Inspectional Observations (Form FDA 483) issued at the close of the inspection, addressing the observations and stating the corrective actions either taken or to be taken. We note that you have committed to a number of corrective actions to address the observations, including revisions to procedures, re-training of current staff, and hiring a Director of Quality Assurance. However, we consider some responses to be inadequate in that examples of new or revised written procedures and validation documentation to support the comments made in your responses were not provided for review. In your response to this letter, we request that you provide complete documentation to demonstrate that the promised corrective actions have been appropriately implemented, including all new or revised procedures. If corrections are on-going, please provide your corrective action plan, with time frames for completion. In addition, where you dispute the accuracy of the investigators' observations, please provide evidence sufficient to support your position. For example, with regard to your response to Observation #1 in your November 12, 2002 response letter, please provide support for your position that backup disks verify that donation dates and testing dates match for the additional [redacted] samples. We will be glad to discuss the violations and your corrective actions in more detail during the meeting that you requested.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products produced and distributed by your blood bank are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to do so may result in administrative and/or regulatory action without further notice. Such action includes, but is not limited to, license suspension and/or revocation, seizure and/or injunction.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including examples of any documentation showing that corrections have been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to James C. MacLaughlin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth St., N.E., Atlanta, Georgia 30309, telephone (404) 253-1220.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District